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Niacin and contribution to normal energy-yielding metabolism: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

Abstract

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to niacin and contribution to normal energy-yielding metabolism. The Panel considers that niacin, the food constituent that is the subject of the health claim, is sufficiently characterised. Contribution to normal energy-yielding metabolism is a beneficial physiological effect. The Panel has previously assessed a claim on niacin and contribution to normal energy-yielding metabolism with a favourable outcome. The target population was the general population. The Panel considers that the role of niacin in contributing to normal energy-yielding metabolism applies to all ages, including infants and young children (from birth to three years). The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and contribution to normal energy-yielding metabolism. The following wording reflects the scientific evidence: 'Niacin contributes to normal energy-yielding metabolism.' The target population is infants and young children up to three years of age.

Keywords: niacin, vitamin B3, infants, children, energy-yielding metabolism, health claims

Requestor: Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE)

Question number: EFSA-Q-2008-185

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Summary

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to niacin and contribution to normal energy-yielding metabolism.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims.

The food constituent that is the subject of the health claim is niacin, which is an essential nutrient and can be measured in foods by established methods. The Panel considers that niacin is sufficiently characterised.

The claimed effect proposed by the applicant is 'plays an important role in the energy metabolism of food'. The target population proposed by the applicant is infants and young children from birth to three years of age. The Panel considers that contribution to normal energy-yielding metabolism is a beneficial physiological effect.

The Panel has previously assessed a claim on niacin and contribution to normal energy-yielding metabolism with a favourable outcome. The target population was the general population. The Panel considered that niacin plays a functional role in energy-yielding metabolism. The Panel considers that the role of niacin in contributing to normal energy-yielding metabolism applies to all ages, including infants and young children (from birth to three years).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and contribution to normal energy-yielding metabolism.

The Panel considers that the following wording reflects the scientific evidence: 'Niacin contributes to normal energy-yielding metabolism.'

In order to bear the claim, follow-on formulae should comply with the criteria for the composition of follow-on formulae as laid down in Directive 2006/141/EC; nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria for the composition of these foods as laid down in Directive 1999/21/EC; processed cereal-based foods for infants and young children should comply with the criteria for the composition of these foods as laid down in Directive 2006/125/EC; and other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for the nutritional labelling for foods intended for infants and young children as laid down in Directive 2006/141/EC. The target population is infants and young children up to three years of age. Tolerable Upper Intake Levels have been established for free nicotinic acid (2 mg/day) and for nicotinamide (150 mg/day) for young children aged one to three years.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006[1] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

1.2. Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: niacin and contribution to normal energy-yielding metabolism.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of niacin, a positive assessment of its safety or a decision on whether niacin is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

1.3. Additional information

A claim on niacin and contribution to normal energy-yielding metabolism has previously been assessed by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) with a favourable outcome (EFSA NDA Panel, 2009).

2. Data and Methodologies

2.1. Data

2.1.1. Information provided by the applicant

Food/constituent as stated by the applicant:

- According to the applicant, the food constituent for which the claim is made is vitamin B_3 (niacin).

Health relationship as claimed by the applicant:

- According to the applicant, vitamin B_3 plays an important role in the energy metabolism of food.

Wording of the health claim as proposed by the applicant:

- The applicant has proposed the following wording for the health claim: 'Vitamin B_3 (niacin) is needed to release energy from foods'. As equivalent alternative wordings, the applicant has

[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

also proposed: 'niacin (vitamin B_3) helps release the energy from foods'; 'niacin (vitamin B_3) is needed for the release of energy from proteins, fats and carbohydrates'; 'niacin (vitamin B_3) helps in the metabolism of carbohydrates, proteins and fats'; and 'niacin (vitamin B_3) supports energy metabolism'.

Specific conditions of use as proposed by the applicant:

- The target population proposed by the applicant is infants and young children from birth to three years of age.
- According to the applicant, the quantities needed to achieve the claimed effect are as follows:
  - For follow-on formulae, the content of vitamin B_3 should be within the range set in Directive 2006/141/EC.
  - For Foods for Special Medical Purpose for infants and young children, the content of vitamin B_3 should be within the range set in Directive 1999/21/EC, unless that is contrary to the intended use of the product.
  - For processed cereal-based foods and baby foods, the content of vitamin B_3 should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/125/EC, i.e. 15 % of 9 mg of niacin equivalent (1.35 mg of niacin equivalent) per 100 g or 100 mL serving, as reconstituted.
  - For the other foods intended for infants and young children, the content of vitamin B_3 should reach at least 15 % of the Nutrient Reference Values set in Directive 2006/141/EC, i.e. 15 % of 7 mg (1.05 mg) per 100 mL product ready for use.

2.1.2. Data provided by the applicant

The applicant provided a health claim application on niacin and contribution to normal energy-yielding metabolism pursuant to Article 14 of Regulation 1924/2006. The application was presented in a common and structured format as outlined in the scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2011a).

As outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, it is the responsibility of the applicant to provide the totality of the available evidence (EFSA NDA Panel, 2011b).

2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b).

3. Assessment

3.1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is niacin, which is an essential nutrient and can be measured in foods by established methods.

Preformed niacin occurs naturally in foods as nicotinamide or the derived pyridine nucleotide coenzymes (nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate) or as nicotinic acid. Niacin can also be synthesised in the body from dietary tryptophan. Niacin is the common term for nicotinamide and nicotinic acid, and is authorised for addition to foods (Annex II of

Regulation (EC) No 1925/2006,[2] Annex II of Directive 2002/46/EC,[3] Annex III of Directive 2006/141/EC,[4] Annex IV of Directive 2006/125/EC[5] and Directive 2001/15/EC[6]).

This evaluation applies to niacin naturally present in foods and those forms authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006, Annex II of Directive 2002/46/EC, Annex III of Directive 2006/141/EC, Annex IV of Directive 2006/125/EC and Directive 2001/15/EC).

The Panel considers that the food constituent, niacin, which is the subject of the health claim, is sufficiently characterised.

3.2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is 'plays an important role in the energy metabolism of food'. The target population proposed by the applicant is infants and young children from birth to three years of age.

The Panel considers that contribution to normal energy-yielding metabolism is a beneficial physiological effect.

3.3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on niacin and contribution to normal energy-yielding metabolism with a favourable outcome (EFSA NDA Panel, 2009). The target population was the general population.

The Panel considered that niacin plays a functional role in energy-yielding metabolism (EFSA NDA Panel, 2009).

The Panel considers that the role of niacin in contributing to normal energy-yielding metabolism applies to all ages, including infants and young children (from birth to three years).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of niacin and contribution to normal energy-yielding metabolism.

3.4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: 'Niacin contributes to normal energy-yielding metabolism.'

3.5. Conditions and restrictions of use

The Panel considers that in order to bear the claim:

- follow-on formulae should comply with the criteria for the composition of follow-on formulae as laid down in Directive 2006/141/EC;
- nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria for the composition of these foods as laid down in Directive 1999/21/EC;
- processed cereal-based foods for infants and young children should comply with the criteria for the composition of these foods as laid down in Directive 2006/125/EC;

[2] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.
[3] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.
[4] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Text with EEA relevance. OJ L 401, 30.12.2006, p. 1–33.
[5] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children. OJ L 339, 6.12.2006, p. 16–35.
[6] Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. OJ L 52, 22.2.2001, p. 19–25.

- other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for the nutritional labelling of foods intended for infants and young children as laid down in Directive 2006/141/EC.

Such amounts can be easily consumed as part of a balanced diet. The target population is infants and young children up to three years of age. Tolerable Upper Intake Levels have been established for free nicotinic acid (2 mg/day) and for nicotinamide (150 mg/day) for young children aged one to three years (SCF, 2002).

4. Conclusions

On the basis of the data presented, the Panel concludes that:

- The food constituent, niacin, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'plays an important role in the energy metabolism of food'. The target population proposed by the applicant is infants and young children from birth to three years of age. Contribution to normal energy-yielding metabolism is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of the dietary intake of niacin and contribution to normal energy-yielding metabolism.
- The following wording reflects the scientific evidence: 'Niacin contributes to normal energy-yielding metabolism.'
- In order to bear the claim, follow-on formulae should comply with the criteria for the composition of follow-on formulae as laid down in Directive 2006/141/EC; nutritionally complete foods for special medical purposes intended for use by infants and nutritionally complete foods for special medical purposes other than those intended for use by infants should comply with the criteria for the composition of these foods as laid down in Directive 1999/21/EC; processed cereal-based foods for infants and young children should comply with the criteria for the composition of these foods as laid down in Directive 2006/125/EC; and other foodstuffs intended for infants and young children should provide at least 15 % of the reference values for the nutritional labelling of foods intended for infants and young children as laid down in Directive 2006/141/EC. The target population is infants and young children up to three years of age. Tolerable Upper Intake Levels have been established for free nicotinic acid (2 mg/day) and for nicotinamide (150 mg/day) for young children aged one to three years.

Documentation provided to EFSA

1. Health claim application on 'vitamin B_3 (niacin) plays an important role in the energy metabolism of food' pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0105_FR). Submitted by Specialised Nutrition Europe (formerly IDACE), 31 Avenue des Nerviens, 1040 Brussels, Belgium.

2. This application was received by EFSA on 14 February 2008.

3. The scope of the application was proposed to fall under a health claim referring to children's development and health.

4. On 26 March 2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.

5. On 29 April 2015, EFSA received the missing information as submitted by the applicant.

6. The scientific evaluation procedure started on 3 June 2015.

7. During its meeting on 29 June 2015, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to niacin and contribution to normal energy-yielding metabolism.

References

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2009. Scientific Opinion on the substantiation of health claims related to niacin and energy-yielding metabolism (ID 43, 49, 54), function of the nervous system (ID 44, 53), maintenance of the skin and mucous membranes (ID 45, 48, 50, 52), maintenance of normal LDL-cholesterol, HDL-cholesterol and triglyceride concentrations (ID 46), maintenance of bone (ID 50), maintenance of teeth (ID 50), maintenance of hair (ID 50, 2875) and maintenance of nails (ID 50, 2875) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2009;7(9):1224, 9 pp. doi:10.2903/j.efsa.2009.1224

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011a. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal 2011;9(5):2170, 36 pp. doi:10.2903/j.efsa.2011.2170

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011b. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal 2011;9(4):2135, 24 pp. doi:10.2903/j.efsa.2011.2135

SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on Food on the tolerable upper intake levels of nicotinic acid and nicotinamide (niacin) (expressed on 17 April 2002). Available online: http://ec.europa.eu/food/fs/sc/scf/out80j_en.pdf